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| 09/525,998 | 03/15/2000 | Rudolph Hauptmann | 98/385 F | 1361 |

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EXAMINER

O'HARA, EILEEN B

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1646

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/525,998

Applicant(s)

HAUPTMANN ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-135, 138, 139 and 144-178 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-135, 138, 139 and 144-178 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 07/511,430.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19,20,21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 27-135, 138, 139 and 144-178 are pending in the instant application. Claims 75, 114, 121, 122, 124-128, 131, 132 and 148 have been amended, claims 19-21, 24-26, 136, 137 and 140-143 have been canceled and claims 149-178 have been added as requested by Applicant in Paper Number 18, filed Nov. 18, 2002.

Information Disclosure Statement

2. The information disclosure statement filed November 26, 2000, Paper No. 20, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The Powell reference that was supplied was not the same reference as that listed in the PTO-1449.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Double Patenting

4. Claims 27-148 remain rejected and new claims 149-178 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,294,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to nucleic acids encoding

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polypeptides that are truncations/deletions of the full length TNF receptor polypeptide shown in SEQ ID NO: 2 that retain TNF binding activity (Figure 9 in both application and patent). The truncations/deletions are obvious because the skilled artisan would want to determine and use polypeptides that retain TNF binding activity but may be smaller than the full length polypeptide or other larger truncations. Traversal of the rejection may not be delayed, and arguments after claims are otherwise allowable will not be considered timely.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 41-48, 71-76, 78, 83-86, 89-91, 96, 97 and 104-148 remain rejected and new claims 149-167 and 178 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1 Claims 41-48 and dependent claims 71-74, 76, 78, 83-86, 89-91, 96, 97, 104-167 and 178 are indefinite because the "at least one" language of the claims does not place an upper limit on the extent of the changes to be made.

Applicants traverse the rejection and assert that claim 41-47, 71, 72 and 74 contain an explicit limitation to encompass only those molecules that possess a particular activity, namely, the ability to bind TNF, and that Applicants are under no duty to define, with absolute precision,

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the number of modifications that would be tolerable without destroying the ability of the molecule to bind TNF. Applicants also contend that the requirements of 35 U.S.C. § 112, second paragraph, are met because one of ordinary skill in the art would readily recognize that a molecule having conservative substitutions at every amino acid position would lack this high affinity TNF- α binding activity, and that 35 U.S.C. § 112, second paragraph, only requires that one of ordinary skill in the art would be able to determine which species fall within the scope of the claim, in order for the claim language to be definite.

Applicants' arguments have been fully considered but are not deemed persuasive. Because of the unlimited number of substitutions in the claims, a protein can have a completely different structure and yet still be able to bind TNF- α . The claims are single means claims, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a). Therefore, the claims fail to adequately point out that which Applicant sees as the invention, and the rejection is maintained.

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5.2 Claim 75 remains rejected, because it is not the hybridization conditions that are crucial for stringency, but the wash conditions. The rejection would be withdrawn if the wash conditions recited on page 65, lines 28-31 were included in the claim.

5.3 Claim 167 is indefinite because it is an incomplete method claim. There is no preamble describing the purpose of the method, and no method steps recited to achieve amplification.

Applicants state that claim 167 refers back to claim 155, but it refers back to claim 104.

Additionally, it is not clear what nucleic acid is to be amplified, since the host cell also comprises endogenous nucleic acid molecules as well as the recombinantly introduced nucleic acid molecule. The rejection would be withdrawn if the claim was amended in a similar manner to newly amended claim 132.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 41-47 and 75 (and dependent claims including new claims) remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants traverse the rejection and argue that the specification sets forth the amino acid sequences of a TNF receptor polypeptide and a 161 amino acid portion of this sequence having the ability to bind TNF, and the structural and functional regions of this polypeptide. Applicants assert that the specification teaches techniques for making conservative substitutions, locations

of glycosylation sites, proteolytic cleavage sites and cysteine residues where amino acid substitutions can be made, and contend that they are under no duty under the statute to enumerate all of the species disclosed generically in their specification, particularly where, as here, the structure of the native molecule is disclosed, the types and variants of said structure are generically disclosed, and a functional property of the claimed molecule (TNF binding activity) and assays to assess species for said property are disclosed, and that the specification conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention.

Applicants' arguments have been fully considered but are not deemed persuasive. Although the specification may teach methods of making conservative substitutions and means to assay activity, the claims as written encompass polypeptides that may have very little or no structural similarity to the single disclosed polypeptide, yet may still bind TNF. The instant disclosure of a single core polypeptide, that of SEQ ID NO: 4 with the instantly disclosed specific activity, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. Given the unpredictability of changing amino acids on the activities of proteins, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. Therefore, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

7. No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

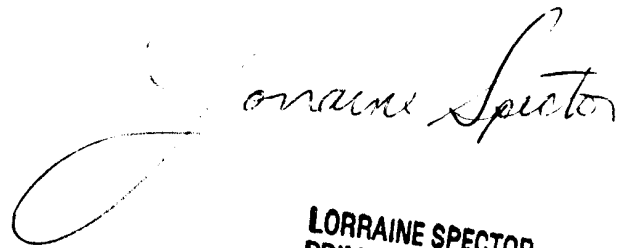
Official papers filed by fax should be directed to (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is written in dark ink and is positioned above a rectangular stamp.

**LORRAINE SPECTOR
PRIMARY EXAMINER**